

REMARKS

Review and reconsideration of the Office Action of April 7, 2003, is respectfully requested in view of the above amendment and the following remarks.

Claims 5 and 7 have been canceled. Claim 15 has been amended to overcome the formality rejection. Claim 16 has been added. Support for Claim 16 can be found on Claim 1 as originally filed. No new matter has been introduced to the claims.

Applicant is submitting herewith a **Second** Declaration under 37 C.F.R. §1.132 to point out a further difference between the aesthetics of the present invention and the aesthetics of the cited prior art. Applicant respectfully requests that the Examiner consider the attached Declaration.

Applicant would like to point out to the Examiner that the claims are directed to method claims, thus all the steps of the Claims of the present invention must be taught in order to teach the present invention.

Applicant is submitting herewith a Declaration Under 37 C.F.R. §1.132, including comparative examples between the composition of the present invention and composition I of the Inagi reference in order to demonstrate the unexpected improvement in evaporation of the composition of the present invention.

As can be seen from the results of the test, the formulation of the present invention shows a remarkable evaporation rate over the composition of the Inagi et al.

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reference. This remarkable evaporation rate allows the kinetic of the formulation to change so that as the proportion of the remaining alcohol is reduced, a more concentrated anesthetic formulation remains present on the skin, which brings a more advanced level of anesthetization. Thus, the delivery rate of the anesthetic is markedly enhanced.

In addition, because the onset of the anesthetic is reduced, the waiting time from the patient is also reduced, thus the patient has a more tolerant attitude.

As a side benefit, the evaporation of the alcohol cools the skin causing the patient to feel a soothing cool, numbing feeling, which psychologically prepares the patient to the effect of the anesthetic.

In the Inagi et al. reference, the acceptable delivery rate of the medicament that needs to be delivered through the skin is lowered because the low evaporation rate of the composition; thus, the anesthetic will take a longer time to act. Furthermore, because of the low evaporation rate, it is possible that alcohol can interact with the patient's skin and cause irritation. As can be seen, the Inagi et al reference does not overcome the problem of the prior art.

Applicant notes that the reference fails to teach that the volatile solvent in an amount between 60-80% as required by new Claim 16.

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Office Action

Turning now to the Office Action in greater detail, the paragraphing of the Examiner is adopted.

Paragraph 1

The Examiner indicated that the request filed on 12/18/2002 for a RCE under 37 CFR 1.114 based on parent Application No. 09/700,102 is acceptable, and a RCE has been established.

Paragraph 2-3 (Status of Application)

The Examiner acknowledges the amendment filed 03/17/02.

Claims 1-15 are pending and presented for the examination.

Paragraph 4 (Double Patenting)

The Examiner objects to Claim 5 under 37 CFR 1.75 as being a substantial duplicate of claim 15.

Applicant notes that the Examiner did not enter amendment B filed on October 7, 2002. Thus, Claim 5 is still pending.

In response, Applicant has canceled Claim 5.

The Examiner objects to Claim 7 under 37 CFR 1.75 as being a substantial duplicate of claim 6.

In response, Applicant has canceled Claim 5.

Accordingly, withdrawal of the rejections is respectfully requested.

Paragraphs 5 and 6 (Formalities)

The Examiner rejects Claim 15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

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out and distinctly claim the subject matter which Applicant regards as the invention.

The position of the Examiner can be found on page 3 of the Office Action.

In response, Applicant has amended Claim 15 to overcome the formality rejection.

Accordingly, withdrawal of the rejections is respectfully requested.

Paragraphs 7 and 8 (Anticipation)

The Examiner rejects Claims 1-15 under 35 U.S.C. 102(e) as being anticipated by Inagi et al (US 6,429,228).

The position of the Examiner can be found on pages 3-5 of the Office Action.

Applicant respectfully traverses.

For a reference to anticipate, it must disclose all the elements of the claim.

Applicant notes that the present application includes 4 independent claims, - Claims 1, 9, 10, and 13.

Compared with present Claims 1, 9, 10, and 13, the method of the present invention differs from the Inagi reference in that the claims require: the step of **evaporating** the volatile solvent from the homogeneous solution.

Applicant notes that the composition of the Inagi reference includes:

2-12 % of the anesthetic

1.0 to 7.0 % of the promoter -fatty acid

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59 to 90 % of alcohol and water in a ratio of 0.5 to 1.2

Applicant notes that the reference fails to teach that the volatile solvent in an amount between 60-80% as required by new Claim 16.

The present inventor believes that the high content of water in the Inagi et al. composition, will not allow the composition to rapidly evaporate from the skin of the patient.

Applicant is submitting herewith a Declaration Under 37 C.F.R. §1.132, including comparative examples between the composition of the present invention and composition I of the Inagi reference in order to demonstrate the unexpected improvement in evaporation of the composition of the present invention.

As can be seen from the results of the test, the formulation of the present invention shows a remarkable evaporation rate over the composition of the Inagi et al. reference. This remarkable evaporation rate allows the kinetic of the formulation to change so that as the proportion of the remaining alcohol is reduced, a more concentrated anesthetic formulation remains present on the skin, which brings a more advanced level of anesthetization. Thus, the delivery rate of the anesthetic is markedly enhanced.

In addition, because the onset of the anesthetic is reduced, the waiting time from the patient is also reduced, thus the patient has a more tolerant attitude.

As a side benefit, the evaporation of the alcohol cools the skin causing the patient to feel a soothing cool, numbing

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feeling, which psychologically prepares the patient to the effect of the anesthetic.

In the Inagi et al. reference, the acceptable delivery rate of the medicament that needs to be delivered through the skin is lowered because the low evaporation rate of the composition; thus, the anesthetic will take a longer time to act. Furthermore, because of the low evaporation rate, it is possible that alcohol can interact with the patient's skin and cause irritation. As can be seen, the Inagi et al reference does not overcome the problem of the prior art.

Favorable consideration and early issuance of the Notice of Allowance are respectfully requested. Should further issues remain prior to allowance, the Examiner is respectfully requested to contact the undersigned at the indicated telephone number.

Respectfully submitted,



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